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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/427,291	10/26/1999	PAUL H BURMEISTER	S63.2-8606	2970

7590

08/19/2003

VIDAS ARRETT & STEINKRAUS PA
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 553439131

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

20

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant No.

09/427,291

Applicant(s)

BURMEISTER ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-32, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-32, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on June 3, 2003 have been entered.

Claim Rejections - 35 USC § 112

Claims 22-32 and 34-35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of claim 22 of "each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state" lacks original support because the original specification did not contemplate presetting the elasticity to elongate as presently claimed.

Since the new matter was part of a preliminary amendment, the subject matter is considered part of the specification filed October 26, 1999. Therefore, a new declaration could be filed which identifies the present application as a continuation-in-part of the parent application and refers to the preliminary amendment presented on the same day; see MPEP 608.04(b) which is incorporated herein by reference.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-32 and 34 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Roubin et al (US 5,827,321) where the effective filing date of the present claims is October 26, 1999.

Response to Arguments

Applicants' arguments filed June 3, 2003 have been fully considered but they are not persuasive.

Applicants argue that the since Figure 11a and 11b show unexpanded and expanded forms of the stent and since the expanded form shows elongated connectors that the elasticity is inherently preset. This has not been found persuasive because the connectors of Figure 11b could have been expanded in many different ways, e.g. by pegs on a balloon to maintain the length, by longitudinal stretching once expanded radially, or by presetting the shape as such. In order to be inherent, it must necessarily flow from the disclosure that the claimed property was present. The specification gives no explanation as to how the expansion of Figure 11a took place; see page 3, lines 23-

25 and page 12, lines 14-19. Therefore, it is not inherent that the elasticity (i.e. the shape in this case) was preset to elongate upon expansion as set forth in the claims.

Again, Applicants argue that Figure 11a and 11b are the only disclosure that supports the claim language, and that this same disclosure was present in parent applications 08/737,492 and 08/246,320. This argument has not been found persuasive because numerous materials and orientations were disclosed for the materials of the stent. For example, in some embodiments, a combination of deformable and spring-like metals is used; see page 4, lines 9-14. In the Nitinol disclosure, there is no* explanation or disclosure that suggests that the shape or elasticity of Figures 11a and 11b can be preset; see page 5, line 5 to page 6, line 2 and page 12, lines 14-19. For these reasons, the argument that this property is inherent is considered unpersuasive.

** The previous Office action contained a typographical omission which left out the modifier "no."*

Response to Amendment

The declaration under 37 CFR 1.132 filed June 3, 2003 is insufficient to overcome the rejection of claims 22-32 and 34-35 based upon 35 USC 112, first paragraph and 35 USC 102(e) [Roubin et al] as set forth in the last Office action because:

The declaration filed under 37 CFR 1.132 filed June 3, 2003 is insufficient to overcome the rejection of claims 22-32 and 34-35 based upon 35 USC 112, first paragraph and 35 USC 102(e) [Roubin et al] as set forth in the last Office action because:

(1). There is no factual support or evidence provided only an opinion of an expert that fails to define what is meant by preset elasticity. Instead, the elasticity or

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superelasticity is said to be preset which allows the shape memory material to self-expand; see paragraph 2 of the declaration. According to the present disclosure, "superelasticity" is merely the elasticity of the shape memory alloy in the austenitic state; see page 5, lines 5-16. "Preset elasticity" is not defined by the Applicant in the present disclosure. Since there is no factual support for the declarant's opinion, the declaration is of little probative value; see MPEP 716.01(b).

(2). Declarations are supposed be directed to statements of fact. Inherency is a legal conclusion based upon the facts present in a particular case. However, the present declaration does not provide facts to back up the declarant's opinion or legal conclusion. For this reason, the declaration is of little probative value.

(3). Since the declaration, and the attorney's discussion thereof, does not provide facts to back up the legal conclusion or does not provide technical reasoning for the same, the case of inherency is not adequately shown. For example, it could be that the device of Figure 11 is made of nitinol and preset with the shape shown in Figure 11b. However, since there are other types of materials disclosed (e.g. spring metals and ductile materials), and other method of expansion disclosed (e.g. by balloon catheterization), it does not necessarily flow that the shape of Figure 11b was preset using Nitinol; see MPEP 2112 which is incorporated herein by reference thereto.

(4). The entire detailed disclosure concerning Figure 11 is on page 3, lines 23-25 and on page 12, lines 14-19 of the present specification. For this disclosure, one cannot be certain that Figure 11b is preset to that shape or whether it is expanded to

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that shape by some other means disclosed in the same disclosure. For these reasons, the case of inherency is clearly not made.

(5). Since no facts were presented with the affidavit, it fails to meet the standard set forth in relevant case law. The following is an excerpt from MPEP 716.01(c) under the heading "Opinion Evidence."

While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. In re Chilowsky, 306 F.2d 908, 134 USPQ 515 (CCPA 1962) (expert opinion that an application meets the requirements of 35 U.S.C. 112 is not entitled to any weight; however, facts supporting a basis for deciding that the specification complies with 35 U.S.C. 112 are entitled to some weight); In re Lindell, 385 F.2d 453, 155 USPQ 521 (CCPA 1967) (Although an affiant's or declarant's opinion on the ultimate legal issue is not evidence in the case, "some weight ought to be given to a persuasively supported statement of one skilled in the art on what was not obvious to him." 385 F.2d at 456, 155 USPQ at 524 (emphasis in original)).

In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). See also In re Oelrich, 579 F.2d 86, 198 USPQ 210 (CCPA 1978) (factually based expert opinions on the level of ordinary skill in the art were sufficient to rebut the prima facie case of obviousness); Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (statement in publication dismissing the "preliminary identification of a human b-NGF-like molecule" in the prior art, even if considered to be an expert opinion, was inadequate to overcome the rejection based on that prior art because there was no factual evidence supporting the statement); In re Carroll, 601 F.2d 1184, 202 USPQ 571 (CCPA 1979) (expert opinion on what the prior art taught, supported by documentary evidence and formulated prior to the making of the claimed invention, received considerable deference); In re Beattie, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992) (declarations of seven persons skilled in the art offering opinion evidence praising the merits of the claimed invention were found to have little value because of a lack of factual support); Ex parte George, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991)

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Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Regan is cited because it discloses that it was known at the time the invention was made to preset a shape in a similar stent; see the abstract for example.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
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